APR - 5 2012 K 113502

1 of 3

510(k) Summary for the
Lutronic Corporation ADVANTAGE Laser System

This 510(k) Summary is being submitted in accordance with the requirements of the SMDA 1990 and 21 CFR 807.92.

1. **General Information**

Submitter:	Lutronic Corporation Room 403-1, 2, 3, 4, 5, 404 Ilsan Technotown 1141-1 Baekseok-dong, Ilsandong-gu, Goyang-si, Gyeonggi-do, 410-722 Republic of Korea
Contact Person:	Maureen O'Connell O'Connell Regulatory Consultants, Inc. 5 Timber Lane North Reading, MA 01864 Telephone: 978-207-1245 Fax: 978-824-2541
Summary Preparation Date:	March 28, 2012

2. **Names**

Device Name:	ADVANTAGE Laser System
Classification Name:	Laser Instrument, Surgical, Powered Product Code: GEX Panel: General & Plastic Surgery

3. **Predicate Device**

Lumenis LightSheer Duet Laser System (K053628)

4. **Device Description**

The ADVANTAGE Laser System is a non-invasive aesthetic laser. The system delivers pulsed infrared laser light with a wavelength ranging from 790-820 nm (805nm nominal) and has two treatment handpieces. The ADVANTAGE H1 handpiece delivers laser energy through a 10 x 10mm tip with a fluence of up to 100 J/cm^2. The settings for this handpiece

are selectable pulse duration from 5 ~ 400ms, selectable fluence from 5 ~ 100J/cm^2 and a pulse repetition rate up to 3 Hz maximum. A second handpiece, the ADVANTAGE H3 handpiece, delivers laser energy through a 10 x 30mm tip, with a fluence of up to 35 J/cm^2. The settings for this handpiece are pulse duration from 30 ~ 400ms, and a pulse repetition rate up to 2 Hz maximum. The complete system consists of a console and handpiece connected to the system cable. In standard use, the handpiece is pressed against the patient's skin and a pulse of light is delivered. To initiate energy output, the system requires redundant activation of the handpiece enable button and the handpiece trigger button while the system is in the Ready mode. The physician is able to control the settings of laser energy from the LCD display on the main console.

5. Indications for Use

The ADVANTAGE Laser System is indicated for use in surgical, aesthetic, and cosmetic applications in the medical specialties of general and plastic surgery, and dermatology. The ADVANTAGE Laser System is intended for use on all skin types (Fitzpatrick skin types I - VI), including tanned skin.

The ADVANTAGE Laser System with H1 Handpiece is indicated for the treatment of vascular lesions, including angiomas, hemangiomas, telangiectasia and other benign vascular lesions, and the treatment for pseudofolliculitis barbae. The ADVANTAGE Laser System with H1 Handpiece is also indicated for hair removal, permanent hair reduction defined as the long-term stable reduction in the number of hairs re-growing after the last treatment measured at 6, 9 and 12 months, and the treatment of benign pigmented lesions and leg veins.

The ADVANTAGE Laser System with H3 Handpiece is indicated for hair removal and permanent hair reduction defined as the long-term stable reduction in the number of hairs re-growing after the last treatment measured at 6, 9 and 12 months.

6. Substantial Equivalence

The ADVANTAGE Laser System is substantially equivalent to the Lumenis LightSheer Duet Laser System. The ADVANTAGE Laser System has the same intended use as the predicate device. Both the ADVANTAGE Laser System and the LightSheer Duet Laser System are intended for use in aesthetic and cosmetic applications within general and plastic surgery and dermatology and both devices are prescription devices which are intended to be used by trained medical personnel. Additionally, the ADVANTAGE Laser System has the same technological characteristics as the predicate device. Both devices are diode laser systems with a nominal output of approximately 800 nm. The ADVANTAGE Laser System's wavelength range is from 790 to 820 nm with a nominal output of 805 nm while the LightSheer Duet Laser System has a wavelength range from 790 to 950 nm with a nominal output of 800 nm. Both devices deliver laser energy to the patient via treatment handpieces. Both devices have two different handpieces with different technical specifications. The fluence, pulse width and repetition rate are within the ranges cleared for

the predicate device. Therefore, the ADVANTAGE Laser System is substantially equivalent to the Lumenis LightSheer Duet Laser System.

7. **Performance Data**
None presented.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Lutronic Corporation
% O'Connell Regulatory Consultants, Inc.
Ms. Maureen O'Connell
5 Timber Lane
North Reading, Massachusetts 01864

APR - 5 2012

Re: K113502
Trade/Device Name: ADVANTAGE Laser System
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: II
Product Code: GEX
Dated: April 2, 2012
Received: April 3, 2012

Dear Ms. O'Connell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act

or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113502

Device Name: ADVANTAGE Laser System

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The ADVANTAGE Laser System with H3 Handpiece is indicated for hair removal and permanent hair reduction defined as the long-term stable reduction in the number of hairs re-growing after the last treatment measured at 6, 9 and 12 months.

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over The Counter Use _____
(Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic, and Restorative Devices

510(k) Number K113502